

REMARKS

Claims 25-32 and 34-41 are pending. Claims 25, 26 and 39 have been cancelled without prejudice. Claims 42 and 43 are newly added. Claims 42 and 43 represent newly cancelled claims 25 and 39, respectively, and have been re-written in order to more clearly describe Applicant's invention. Claims 27, 28, 30, 34, 35, 37, 38 and 40 have been amended to remove their dependency from newly cancelled claims. Support for the amendment, including newly added claims 25 and 39, is found in the specification and claims as originally filed, as discussed below. No new matter has been entered.

Drawings

The office action indicates that that new corrected drawings in compliance with 37 C.F.R. 1.121(d) are required in this application. Accordingly, Applicant has cancelled Figures 1A and 1B, and amended the specification accordingly.

Claim Objections and Rejections

The Office Action states that claim 25 is objected to because of the following informality: the positive recitation in line 1 of "for detecting the presence" should apparently read "for detecting a presence". Claim 25 has been newly cancelled by Applicant rendering the objection moot.

Claim Rejections – 35 USC § 101-Double patenting

The Office action states that should claims 39-41 be found allowable, claims 1 and 34 will be objected to as being a substantial duplicate thereof.

Applicant notes that claim 1 is not pending and therefore its potential objection is rendered moot. Applicant assumes that claim 25 was intended instead of claim 1.

Claim 25 has been newly cancelled by Applicant as described above, rendering the objection moot.

The objection is addressed to the extent that it would apply to newly added claim 42 and claim 34, newly amended to depend from claim 42. Applicants respectfully traverse the objection on the grounds that claim 34 further limits the scope of claim 42 by requiring that the HPV detected be high risk HPV.

Claim Rejections – 35 USC § 102

Claims 25-27 and 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Edens et al. (6,521,190 B1)

Applicant respectfully traverses. Anticipation requires that the purported prior art reference disclose each and every limitation of the claims. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Applicant contends that Edens et al. does not teach each and every limitation of the instant claims as newly amended.

Edens et al. teach:

“A collection apparatus comprising a collection container comprising a first interior portion, second interior portion and third interior portion, wherein the first interior portion of the container extends from an open end to the second interior portion and defines a first central axis; the second interior portion extends inwardly and has a decreasing cross-sectional area from the first interior portion to the third interior portion, and defines a second central axis at an oblique angle with respect to the first central axis, the second interior portion being sized to engage bristles of a brush device having a body of bristles on a shaft and to urge the shaft of the brush device at an angle with respect to the first central axis; the third interior portion extends from the second interior portion and defines a closed end; and the first, second and third interior portions are sized and arranged to form an unencumbered straight line path from the open end to the closed end of the collection container”, emphasis added, claim 1. Also see Figure 2 of US6,521,190.

The method of Edens et al. uses a cervical brush which can fit into the collection device and must be completely removed from the collection device when the sample cells are being collected. Accordingly, in the methods taught by Edens et al., the sample is collected with a brush, and subsequent to sample collection, the brush containing the sample is then positioned

(and stored) in Edens et al.'s claimed collection chamber with cytology fluid at the bottom of the chamber in such a way that a pipette tip can later access the fluid surrounding the brush without being impeded by the presence of the brush. Thus the brush taught by Edens et al. must be separable from the container component of the device.

In contrast, the instant claims require that the brush used for sample collection *be attached* to the retractable inner tube of the recited device. This unitary structure has the net effect that the entire device is used during sample collection. (See Figures 1A and 1B, and paragraphs 20 and 22 of the published instant application). As depicted in the instant specification:

“As shown in FIGS. 1A and 1B, the device comprises a brush attached to an inner tube, and an outer tube that serves as shield to the brush and the inner tube. The brush includes a longitudinal axis that runs through the inner tube and bristles that extend laterally outward from the longitudinal axis. The brush and the inner tube as a whole are called the collection element”, paragraph 0020 of the published application, and

“In the self-sampling method described herein, one preferred embodiment comprises inserting the collection device into the vagina, protruding the collection element out to have the bristles contact with the cervical/vaginal tissues, rotating the inner tube of the collection element, withdrawing the collection element back into the shield, and taking the whole collection device out of the body. The bristles containing the vaginal sample is then immersed into a liquid collection medium”, paragraph 0022 of the published instant application.

Thus, the device used in the method of Edens et al. and the device used in the present method are entirely different. Because the instantly claimed methods for detecting the presence of a human papilloma virus require the use of a device that is structurally distinct from the device used in the methods taught by Edens et al., the teachings of Edens et al are not anticipatory.

Page 5 of the final office action describes the device used in the method of Edens et al. as “comprising a collection element (200) and a shield comprising an outer tube (110) surrounding the collection element, wherein the collection element comprises an inner tube (220) and a brush (210) attached to the inner tube”, referring to Figure 2 of Edens et al.

However, Edens et al. does describes (110) as a collection container, not a tube: “a collection container 110 including an open end 114, a closed end 116, and an interior wall 112”, column 3, lines 20-23. Further, Edens et al. does not describe (220) as an inner tube, “but as a shaft or rod which serves as a handle when taking samples” column 3. lines 14-15.

In contrast, the device of the instant claims contains no shaft or rod that serves as a handle when taking in the instantly claimed method. The device recited in the instant claims comprises a collection element containing a retractable inner tube, and a brush attached to the inner tube with a longitudinal axis and bristles that are substantially perpendicular to the longitudinal axis of the brush. Further, there is no mention of an inner tube in the device of Edens et al.

Paragraph 16 of the final office action asserts that Applicant’s arguments relies on the feature that “the brush must be a separate device” is not recited in the rejected claims. As described above, the instant claims recite that the brush is attached to the inner tube of the device. As such, the brush of the instantly recited brush is not separated from the rest of the device. In contrast, the brush is a component which is separable from the device described by Edens et al.

“A cellular sample is typically obtained from the cervix by gently inserting the cytology brush device 200 until only the bristles closest to the shaft or rod 220 are exposed to the cervical tissue. The brush device 200 is then slowly rotated and removed”, column 4, lines 29-33, US6,521,190.

Figure 2 of Edens et al. shows that the brush is pointed down towards the closed end of the collection apparatus. Edens et al. states “The collection apparatus 100 includes a collection container 110 including an open end 114, a closed end 116, and an interior wall 112”, column 3, lines 20-23. Thus the functional and physical disclosure of the sampling device by Edens et al. clearly indicate that the brush and the collection container are separate, unattached elements.

However, in order to further clarify Applicant’s invention, Applicant has newly amended the instant claims to reflect the feature that the inner tube to which the brush is attached is retractable.

This retractable feature in the structural design of the device encompassed by the instant claims clearly distinguishes it from the device taught by Edens et al. In view of the claim

amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the instant rejection.

Claims Rejections – 35 USC § 103

Claims 28-32 stand rejected as obvious over Edens, in view of Zavada (US2003/0049828).

Applicants respectfully traverse on the grounds that neither Edens et al. alone, nor when combined with Zavada, teach all the limitations of the instant claims as newly amended. Applicants submit that for a determination of obviousness to be proper, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As discussed in the rebuttal to the 102 rejection, Edens et al. does not teach a method for detecting HPV in a vaginal specimen comprising the use of a specimen collection device where a brush is attached to the inner tube of the collection device, as required by the instant claims.

Zavada et al.'s teaching of methods comprising assaying bodily fluids for the presence of MN proteins using antibodies and proteins does not make up for Edens et al.'s not teaching a unitary device as required by the instant claims.

Therefore, Applicants contend that the teachings of Edens et al., either alone or in combination with Zavada et al., do not teach all the limitations of the instant claims. Specifically the limitations that the instantly recited device comprise a collection element with a retractable inner tube, and a brush attached to the inner tube with a longitudinal axis and bristles that are substantially perpendicular to the longitudinal axis of the brush, is not taught or suggested by either Zavada nor Edens et al., either individually or when combined.


In view of the distinct structural and functional features of the instantly recited device from that taught in the references cited in the Office Action, Applicants contend the instant claims are not anticipated nor made obvious by the cited references.

Conclusion

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

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Respectfully submitted,

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